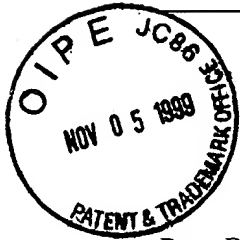


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: K. Kasper, et al. Examiner: Not Yet Assigned
Serial No.: 09/368,010 Group Art Unit:
Filed: August 3, 1999 Docket: 14598-41
Due Date: November 3, 1999
Title: MONOCLONAL ANTIBODIES TO TACROLIMUS AND IMMUNOASSAY METHODS FOR TACROLIMUS



CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on November 3, 1999.

By: Laura Martinez
Laura Martinez

Box: DDS Non Fee
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Information Disclosure Statement, Form 1449 including 12 references
- ☒ Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 16-2230. A duplicate of this sheet is enclosed.

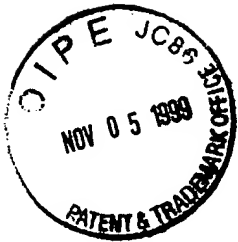
OPPENHEIMER WOLFF & DONNELLY LLP
2029 Century Park East, 38th Floor
Los Angeles, CA 90067-3024
(310) 788-5000

By: Michael B. Farber
Name: Michael B. Farber
Reg. No.: 32,612
MF/lm

RECEIVED

NOV 8 1999

TECH CENTER 1600/2900

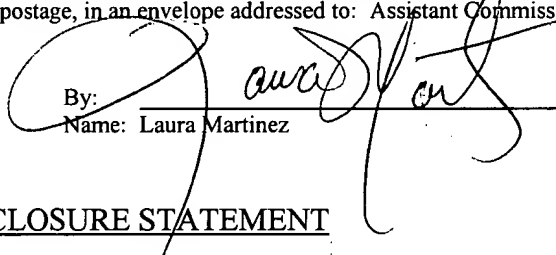


14598-41

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: K. Kasper et al. Examiner: Not Assigned
Serial No.: 09/368,010 Group Art Unit:
Filed: August 3, 1999 Docket: 14598-41
Due Date: November 3, 1999 Date Mailed: November 3, 1999
TITLE: MONOCLONAL ANTIBODIES TO TACROLIMUS AND IMMUNOASSAY
METHODS FOR TACROLIMUS

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on November 3, 1999.

By: 
Name: Laura Martinez

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner
for Patents
Washington, DC 20231

Dear Sir:

This document is an Information Disclosure Statement to the above-cited patent application.

Attached hereto is at least one Form PTO-1449 listing documents believed relevant to the subject application. The submission of the following information is not intended, nor should it be construed, to constitute an admission that any patent, article, or other information referred to herein is "prior art" unless specifically designated as such. In accordance with 37 C.F.R. § 1.97(b) the filing of this information shall not be construed to mean that a search has been made or that no other material information may exist. Neither should its

submission be construed to indicate that a thorough search should not be conducted by the Examiner.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.56, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned so that any deficiencies can be remedied.

This Information Disclosure Statement is being submitted before the mailing of an Office Action on the merits on the above-identified application. Therefore, no fee is due for submission of this Information Disclosure Statement, pursuant to 37 C.F.R. § 1.97(b)(1). If an Office Action on the merits has been mailed prior to the submission of this Information Disclosure Statement, authorization is hereby given to charge the required fee under 37 C.F.R. § 1.197(c) and 37 C.F.R. § 1.17(p) to Deposit Account No. 16-2230.

A copy of each document is enclosed. Some of the documents may have markings thereon. No significance is meant to be attached to the markings. These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import as the order thereof is completely fortuitous.

It is respectfully requested that these documents be: (1) fully considered by the Patent and Trademark Office during the examination of this application; and (2) represented on any patent which may issue on the application. Applicants respectfully request that copies of the PTO-1449 forms, as considered and initialed by the Examiner, be returned with the next communication.

Exhibit 1 is a United States patent, U.S. Patent No. 3,817,837 to Rubinstein et al., issued June 18, 1974.

Exhibit 2 is a United States patent, U.S. Patent No. 5,532,137 to Niwa et al., issued July 2, 1996.

Exhibit 3 is a European Patent publication, EPO 0293892 by Niwa et al., published December 7, 1988.

Exhibit 4 is a publication, G. Wiederrecht et al., "The Mechanism of Action of FK-506 and Cyclosporin A," Ann. N.Y. Acad. Sci. 696:9-19 (1993).

Exhibit 5 is a publication, M.L. Cleary & J. Sklar, "Lymphoproliferative Disorders in Cardiac Transplant Recipients are Multiclonal Lymphomas," Lancet 2:49-493 (1984).

Exhibit 6 is a publication, L.J. Swinnen et al., "Increased Incidence of Lymphoproliferative Disorder After Immunosuppression with a Monoclonal Antibody OKT3 in Cardiac-Transplant Recipients," N. Engl. J. Med. 323:1723-1728 (1990).

Exhibit 7 is a publication, B.Z. Katz et al., "Latent and Replicating Forms of Epstein-Barr Virus DNA and Lymphomas in Lymphoproliferative Diseases," J. Infect. Dis., 160:589-598 (1989).

Exhibit 8 is a publication, J.S. Huston et al., "Protein Engineering of Antibody Binding Sites: Recovery of Specific Activity in an Anti-Digoxin Single-Chain Fv Analog Produced in *Escherichia coli*," Proc. Natl. Acad. Sci. USA 85:5879-5883 (1988)

Exhibit 9 is a publication, G.T. Hermanson, "Bioconjugate Techniques" (Academic Press, San Diego, 1996), pp. 570-592.

Exhibit 10 is a publication, P.J. Taylor et al., "Sensitive, Specific Quantitative Analysis of Tacrolimus (FK506) in Blood by Liquid Chromatography-Electrospray Tandem Mass Spectrometry," Clin. Chem. 42: 279-285 (1996).

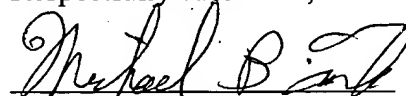
Exhibit 11 is a publication abstract, H.J. Jeong et al., "New Monoclonal Antibody for the Immunosuppressive Drug Tacrolimus," Ther. Drug Monit. 21: 444 (August 1999), Abstract No. 65.

Exhibit 12 is a publication abstract, V.W. Armstrong et al., "Evaluation of an EMIT[®] Tacrolimus Assay: Comparison with Pentamer Formation Assay and Tacrolimus II MEIA," Ther. Drug Monit. 21: 448 (August 1999), Abstract No. 80.

Dated:

November 3, 1999

Respectfully submitted,



Michael B. Farber

Registration No. 32,612

OPPENHEIMER WOLFF & DONNELLY LLP

2029 Century Park East, 38th Floor
Los Angeles, California 90067-3024

Direct No.: (310) 788-5104

Fax No.: (310) 788-5100